Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

12608

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# MEDWATCH

For VOLUNTARY reporting by health professionals of adverse events and product problems

Form Approved- OMB No. 0910-0291 Expires 12/31/98
See OMB statement on reverse

FDA use only
Triage unit sequence # 12796
12608

(FSAN)

Page ___ of ___

## A. Patient information

| 1. Patient identifier | 2. Age at time of event: UKN / Date of birth: | 3. Sex | 4. Weight |
|---|---|---|---|
| [redacted] In confidence | | ☐ female ☒ male | UK lbs / kgs |

## B. Adverse event or product problem

1. ☒ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)
- ☐ death (mo/day/yr)
- ☐ life-threatening
- ☐ hospitalization
- ☐ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☒ other: ____

3. Date of event (mo/day/yr): 10/14/97

4. Date of this report (mo/day/yr): 10/24/97

5. Describe event or problem
THE REPORTER STATED THAT THE PATIENT HAD SEVERE WITHDRAWAL SYMPTOMS AFTER THE DISCONTINUATION OF A SUPPLEMENT CALLED "RIPPED FUEL" GEL CAP. THE PATIENT HAD SIGNS OF DEPRESSION AND CAFFEINE FATIGUE REBOUND.

RECEIVED OCT 13, 1997

6. Relevant tests/laboratory data, including dates
NONE

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)
THE PATIENT HAS NO MEDICAL HISTORY. NO KNOWN ALLERGIES.

## C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#1 RIPPED FUEL GEL CAP (TWIN LABS)
#2

2. Dose, frequency & route used
#1 2 TABS 3 X DAY
#2

3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1 1 1/2 YEARS
#2

4. Diagnosis for use (indication)
#1 INCREASE ENERGY/STRENGTH
#2

5. Event abated after use stopped or dose reduced
#1 ☐ yes ☒ no ☐ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

6. Lot # (if known)
#1 UKN
#2

7. Exp. date (if known)
#1 UKN
#2

8. Event reappeared after reintroduction
#1 ☐ yes ☐ no ☒ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

9. NDC # (for product problems only)
– –

10. Concomitant medical products and therapy dates (exclude treatment of event)
TETRACYCLINE

## D. Suspect medical device

1. Brand name

2. Type of Device

3. Manufacturer name & address
REC'D. OCT 27 1997

4. Operator of device
- ☐ health professional
- ☐ lay user/patient
- ☐ other

5. Expiration Date (mo/day/yr)

6.
model #
catalog # MEDWATCH CTU
serial #
lot #
other #

7. If implanted, give date (mo/day/yr)

8. If explanted, give date (mo/day/yr)

9. Device available for evaluation? (Do not send to FDA)
☐ yes ☐ no ☐ returned to manufacturer on ____ (mo/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

## E. Reporter (see confidentiality section on back)

1. Name & Address [redacted] phone # [redacted]

2. Health professional? ☒ yes ☐ no

3. Occupation: MD

4. Also reported to
- ☐ manufacturer
- ☐ user facility
- ☐ distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an " X " in this box. ☒

FDA

Mail to: MEDWATCH, 5600 Fishers Lane, Rockville, MD 20852-9787 or FAX to: 1-800-FDA-0178

FDA Form 3500 (1/98)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

**TAKEN BY TELEPHONE**

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